

The

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 05-403)

In the Application of:

Christophe Revirron

Serial No.: 10/536,939

Filing Date: May 27, 2005

For: Use of Levocetirizine for the Treatment of

Persistent Allergic Rhinitis

Examiner: TBD

Group Art Unit: TBD

Confirmation No.: TBD

TRANSMITTAL LETTER

Commissioner for Patents P.O. Box 1450 Álexandria, VA 22313-1450

Dear Sir:

In regard to the above identified application,

- 1. We are transmitting herewith the attached:
 - a) Information Disclosure Statement:
 - b) PTO Form 1449 and 12 references cited therein; and
 - c) return receipt postcard.
- 2. With respect to fees:
 - a) A fee is not required at this time.
 - b) Please charge any underpayment or credit any overpayment our Deposit Account, No. 13-2490.
- 3. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on December 16, 2005.

Date: December 16, 2005

Michael S. Greenfield Registration No. 37,142

Respectfully submitted

McDonnell Boehnen Hulbert & Berghoff LLP 300 South Wacker Drive Chicago, IL 60606 (312)913-0001



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INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents and Trademarks P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Copies of the cited references are enclosed. These references are also listed on the enclosed PTO Form 1449.

This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

Applicants do not believe any fee is due with this submission. If this belief be in error and the Patent Office determines that the fee prescribed in the relevant portion of 37 C.F.R. Section 1.97 is applicable, the undersigned attorney by his signature hereby authorizes any such fee to be debited from Deposit Account 13-2490.

FOREIGN PATENT DOCUMENTS

1. WO Patent No. WO 94/06429, published March 31, 1994.

CERTIFICATE OF MAILING (37 C.F.R. 1.8a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1456, Alexandria, VA 22313-1459, on December 16, 2005.

Date: December 16, 2005

Aichael S) Greenfield

OTHER DOCUMENTS

- 2. Bousquet, et al., "The management of allergic rhinitis symptoms in the pharmacy", Aria in the Pharmacy, Allergic Rhinitis and it's Impact on Asthmas, pp. 1-25 FINAL DRAFT.
- 3. Storms, William W., "Rethinking our approach to allergic rhinitis management", Ingentaconnect, Annals of Allergy, Asthma and Immunology, Vol. 88, Supplement 1, April 2002, Abstract.
- 4. Gensthaler et al., "R-Enantiomer gegen Allergien" Levocetirizin XP-001147797 pp. 35-36.
- 5. Juniper, Elisabeth F., "Measuring Health-Related Quality of Life in Rhinitis", J Allergy Clin Immunol, February 1997.
- 6. Juniper, Elizabeth F. and Guyatt, G.H., "Development and testing of a new measure of health status for clinical trials in rhinoconjunctivitis", Clinical and Experimental Allergy, Vol. 21, pp. 77-83, submitted 6 June 1990; revised 13 August 1990; accepted 13 August 1990.
- 7. Gandon, J.M and Allain, H., "Lack of effect of single and repeated doses of levocetirizine, a new antihistamine drug, on cognitive and psychomotor functions in healthy volunteers". 2002 Blackwell Science Ltd Br J. Clin Pharmacol, 54, 51-58.
- 8. Grant et al., "A double-blind, randomized, single-dose, crossover comparison of levocetirizine with ebastine, fexofenadine, loratadine, mizolastine, and placebo: suppression of histamine-induced wheal-and flare response during 24 hours in healthy male subjects, Annals of Allergy, Asthma & Immunology. pp. 190-197.
- 9. Mees et al., "Efficacy and safety of levocetirizine in seasonal allergic rhinitis", PubMed, Acta Otorhinolaryngol Belg. 2001;55(4):305-12.
- 10. Doctor's Guide, "Xyzal (Levocetirizine) Launched in England for Allergic Rhinitis", http://www.pslgroup/dg/207766.htm, October 1, 2001.
- 11. Doctor's Guide, "Germany Approves Antihistamines Xyzal and Xusal (Levocetirizine)", http://www.pslgroup.com/dg/1EFC66.htm, January 16, 2001.
- 12. Salumun, et al., "Antihistamines in late-phase clinical development for allergic disease", Expert Opinion, Investigation Drugs (2002) 11(2):259-273.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff

Date: December 16, 2005

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FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.	Serial No.	
OTPE 48 INFORMATION DISC DEC 9.2 2005 STATEMENT BY API	LOSURE	05-403	10/536,939	
(Use several sheets		Applicant:		
		Christophe Revirron		
		Filing Date:		
		May 27, 2005	TBD	

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
					1 - 3 - V	

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
1.	WO 94/06429	31 March 1994	WO	31	495	/	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

2.	Bousquet, et al., "The management of allergic rhinitis symptoms in the pharmacy", Aria in the Pharmacy, Allergic Rhinitis and it's Impact on Asthmas, pp. 1-25 FINAL DRAFT.
3.	Storms, William W., "Rethinking our approach to allergic rhinitis management", Ingentaconnect, Annals of Allergy, Asthma and Immunology, Vol. 88, Supplement 1, April 2002, Abstract.
4.	Gensthaler et al., "R-Enantiomer gegen Allergien" Levocetirizin XP-001147797 pp. 35-36.
5.	Juniper, Elisabeth F., "Measuring Health-Related Quality of Life in Rhinitis", J Allergy Clin Immunol, February 1997.
6.	Juniper, Elizabeth F. and Guyatt, G.H., "Development and testing of a new measure of health status for clinical trials in rhinoconjunctivitis", Clinical and Experimental Allergy, Vol. 21, pp. 77-83, submitted 6 June 1990; revised 13 August 1990; accepted 13 August 1990.

	7.		and repeated doses of levocetirizine, a new antihistamine lthy volunteers". 2002 Blackwell Science Ltd Br J. Clin	
	8.	Grant et al., "A double-blind, randomized, single-dose, crossover comparison of levocetirizine with ebastine, fexofenadine, loratadine, mizolastine, and placebo: suppression of histamine-induced wheal-and flare response during 24 hours in healthy male subjects, Annals of Allergy, Asthma & Immunology. pp. 190-197.		
	9.	Mees et al., "Efficacy and safety of levocetirizine in seasonal allergic rhinitis", PubMed, Acta Otorhinolaryngol Belg. 2001;55(4):305-12.		
	10.	Doctor's Guide, "Xyzal (Levocetirizine) Launched in England for Allergic Rhinitis", http://www.pslgroup/dg/207766.htm, October 1, 2001.		
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	12.	Salumun, et al., "Antihistamines in late-phase clinical development for allergic disease", Expert Opinion, Investigation Drugs (2002) 11(2):259-273.		
EXAMINER			DATE CONSIDERED	

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.